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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,838	12/22/2005	Hideki Kubota	281748US0PCT	2991
22850	7590	11/17/2008	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			OH, TAYLOR V	
			ART UNIT	PAPER NUMBER
			1625	
			NOTIFICATION DATE	DELIVERY MODE
			11/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/561,838	Applicant(s) KUBOTA ET AL.	
	Examiner Taylor Victor Oh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

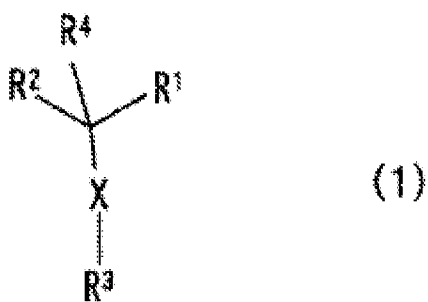
The Lack of Unity

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

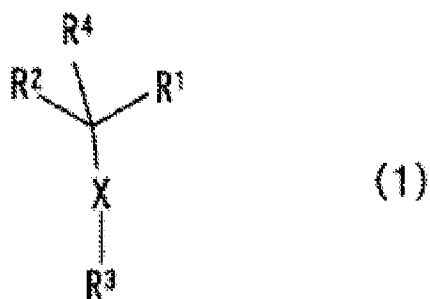
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-18, is drawn to the following compound formula (I) containing all R¹ and R² and R³ which are a pyridyl moiety and its pharmaceutical composition as disclosed below :



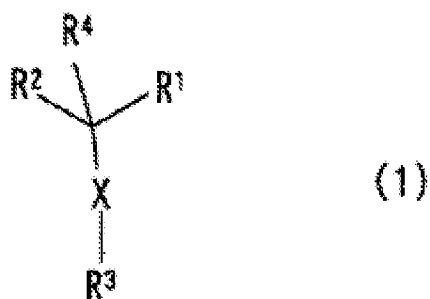
Group II, claims 1-18, is drawn to the following compound formula (I) containing all R¹ and R² and R³ which are a thienyl moiety and its pharmaceutical composition as disclosed below :

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Group III, claims 1-18 , is drawn to the following compound formula (I)

containing all R₁ and R₂ and R₃ which are a non-heteroaryl , non-heterocyclic or phenyl moiety and its pharmaceutical composition as disclosed below :

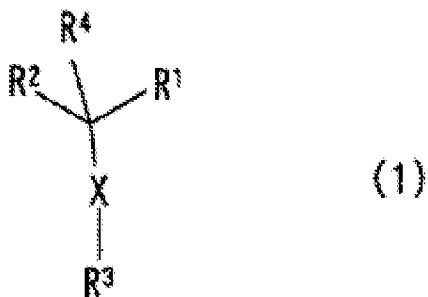


Group IV, claims 1-18 , is drawn to the following compound formula (I)

containing other types of aromatic heteroaryl , monocyclic heterocyclic compounds, i.e. pyrrolidinyl, imidazolyl, isoxazoly, thiazolyl,thiomorpholinyl, furanyl, , thiranyl, tetrahydropyranyl,

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benzopyranyl, dioxolanyl, piperazinyl, morphole, isothiazolidinyl, thiophenyl and its pharmaceutical composition as disclosed below :



Group V, claims 19-22, is drawn to the method for treatment or preventing Alzheimer disease by using the compound formula (I) .

A. The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (" requirement of unity of invention ").

PCT Rule 13.2 states " Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression " special technical features" shall mean those technical

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features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In the instant case, the invention of Group I is directed to the compound formula (I) containing all R1 and R2 and R3 which are a pyridyl moiety, and its pharmaceutical composition, whereas the invention II is related to the compound formula (I) containing all R1 and R2 and R3 which are a thienyl moiety and its pharmaceutical composition. They have different modes of operation, different functions or different effects because each of their reactants has a completely different chemical structure with respect to the core structure. For example, the reactant containing a hetero group has been known to have a different reactivity or a different effect in comparison with the one with the non-hetero groups. Therefore, Group I and Group II are unrelated to each other. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds. Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the compound formula (I) containing all R1 and R2 and R3 which are a pyridyl moiety, and its pharmaceutical composition, whereas the invention III is related to the compound formula (I) containing all R1 and R2 and R3 which are a non-heteroaryl, non-heterocyclic or phenyl moiety and its pharmaceutical composition. They have different modes of operation, different functions or different effects because each of their reactants has a completely different chemical structure with respect to the core

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structure. For example, the reactant containing a hetero group has been known to have a different reactivity or a different effect in comparison with the one with the non-hetero groups. Therefore, Group I and Group II are unrelated to each other. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds. Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the compound formula (I) containing all R1 and R2 and R3 which are a pyridyl moiety, and its pharmaceutical composition, whereas the invention IV is related to the compound formula (I) containing all various R1 and R2 and R3 which are pyrrolidinyl, imidazolyl, isoxazolyl, thiazolyl, thiomorpholinyl, furanyl, , thiranyl, tetrahydropyranyl, benzopyranyl, dioxolanyl, piperazinyl, morphole, isothiazolidinyl, thiophenyl and its pharmaceutical composition. They have different modes of operation, different functions or different effects because each of their reactants has a completely different chemical structure with respect to the core structure. For example, the reactant containing a hetero group has been known to have a different reactivity or a different effect in comparison with the one with the non-hetero groups. Therefore, Group I and Group II are unrelated to each other. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds. Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the compound formula (I) containing all R1 and R2 and R3 which are a pyridyl moiety and its pharmaceutical composition, whereas the invention V is related to the method for treatment or preventing Alzheimer disease by using the compound formula (I). The prior art Fasman (US 5,523,295) discloses the followings:

A method for treating or preventing Alzheimer's disease in a mammal is described. A silicon compound for inhibiting interaction between aluminum and β -amyloid or neurofilament protein is provided. The silicon compound is administered to a mammal in need of such treatment to cause this inhibition to occur.

This compound is structurally unrelated to the claimed compounds of formula (I). Therefore, there is no special technical feature of Group I required in Group V. There is no single general inventive concept and no unity of invention for the method or the processes as defined in 37 CFR 1.475.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

37 CFR 1.475 states that a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combination of categories:

- a. A product and a process specially adapted for the manufacture of said product;
or
- b. A product and a process of use of said product; or
- c. A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- d. A process and an apparatus or means specially designed for carrying out the said process; or
- e. A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

B. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taylor Victor Oh/
Primary Examiner, Art Unit 1625
11/10/08

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